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ABSTRACT

Background: In recent decades, there has been considerable international attention aimed at improving the safety of hospital care, and more recently this attention has broadened to include primary medical care. In contrast, the safety profile of primary care dentistry remains poorly characterized.

Objectives: We aimed to describe the types of primary care dental patient safety incidents reported within a national incident reporting database and understand their contributory factors and consequences.

Methods: We undertook a cross-sectional mixed-methods study, which involved analysis of a weighted randomized sample of the most severe incident reports from primary care dentistry submitted to England and Wales' National Reporting and Learning System. Drawing on a conceptual literature-derived model of patient safety threats that we previously developed, we developed coding frameworks to describe and conduct thematic analysis of free text incident reports and determine the relationship between incident types, contributory factors and outcomes.

Results: Out of 2,000 reports sampled, 1,456 were eligible for analysis. Sixty types of incidents were identified and organized across pre-operative (40.3%; n=587), intra-operative (56.1%; n=817) and post-operative (3.6%; n=52) stages. The main sources of unsafe care were *delays in treatment* (344/1,456; 23.6%), *procedural errors (excluding wrong-tooth extraction)* (227/1,456; 15.6%), *medication-related adverse incidents* (161/1,456; 11.1%), *equipment failure* (90/1,456; 6.2%) and *x-ray related errors* (87/1,1456; 6.0%). Of all incidents that resulted in a harmful outcome (n=77; 5.3%), over half were due to wrong tooth extractions (37/77; 48.1%) mainly resulting from distraction of the densist. As a result of this type of incident, 34 of the 37 patients (91.9%) examined required further unnecessary procedures.

Conclusions: Flaws in administrative processes need improvement since they are the main cause for patients experiencing delays in receiving treatment. Checklists and standardization of clinical procedures have the potential to reduce procedural errors and avoid over-utilization of services. Wrong-tooth extractions should be addressed through focused research initiatives and encouraging policy development to mandate learning from serious dental errors like never events.

Keywords: Ambulatory dentistry, community dentistry, patient safety, patient safety incidents, primary dental care.

Introduction

Healthcare-associated harm is estimated to occur in between 3% and 16% of hospital admissions.[1-3] In primary care, between two and three patient safety incidents occur per every 100 encounters;[4] with approximately 4% of these primary care incidents resulting in severe harm.[(4)] Over the past 20 years, healthcare organizations, researchers and policymakers around the world have begun to pay increasing attention to patient safety. Accumulated evidence about the extent of harm and underlying causes has been translated into interventions designed to improve the safety of the healthcare system,[5] such as incident reporting systems.[6, 7] The need to develop and introduce these systems was signalled within the reports *To Err is Human*[8] and *An Organisation with a Memory*.[9] Their fundamental role is "*to enhance patient safety by learning from failures of the health care system*".[10] The analysis of the retrieved data from these systems provide valuable insights about the trends and patterns of patient safety hazards at an organizational level[11] and can allow the identification of priorities for intervention.[12] This information further bring opportunities to develop evidence-based models for safe practices and support for education and learning.[11] Compared with other data sources,[13] incident reporting systems can provide continuous, near real-time insights about diverse patient safety incidents, including near misses.

Patient safety in primary care is a field that remains largely unexplored.[14, 15] In the United Kingdom (UK), initial mixed-methods studies analyzing general practice incident reports from the National Reporting and Learning System (NRLS) have shown their utility to categorize PSIs and identify patterns of contributory incidents and contributory factors.[16-20] However, patient safety research in dentistry is in its early development. A recent scoping review on PSIs and adverse events in dentistry shows that, over the past 20 years, this field has not employed standardized patient safety terminology and used varying study designs and methodologies to investigate unsafe care.[21] As a result, the current evidence cannot be generalised and provide reliable estimates of the frequency of incidents, their causes, or the outcomes of these errors. To standardize patient safety research in dentistry, recent studies have started to focus on the characterization of patient safety incidents,[22] including adverse events.[23, 24] Only two studies have explored primary dental care data from national incident reporting systems,[22, 25] from which one built an initial classification.[(22)] Although these classification systems provide a starting point, they should be further expanded/refined and include a clear distinction between incidents, their causes as well as the outcomes affecting the patient (adverse events) and healthcare system. Therefore, we aimed, firstly, to explore data from the NRLS to identify emerging themes and then develop categories and subcategories of incidents, their contributory factors, outcomes and degree of harm. Secondly, we aimed to describe incident patterns through identification of frequencies of the relationships between incidents and contributory factors. Thirdly, we aimed to describe the more frequent and harmful reported incidents.

Methods

We conducted a two-stage cross-sectional, mixed-methods study of the NRLS with a selected sample of reports from primary dental care for analysis. We combined qualitative methods and iterative generation of data summaries using descriptive statistical and thematic analysis methods.[26]

Data source

The NRLS is a national reporting system created in 2003 for the NHS in England and Wales by the former National Patient Safety Agency (NPSA). It is one of the most comprehensive reporting systems in the world.[27, 28] It consists of a database of incident reports submitted by National Health Service (NHS) healthcare organizations, however, patients and other members of the public can also submit online reports directly to the NHS. The NHS definition for the reported patient safety incidents refers to *"any injury or unexpected incident that could have or did lead to harm for one or more patients receiving NHS-funded healthcare."*[29] Although reporting was initially voluntary, it has since 2010 been mandatory to report any incidents that resulted in severe patient harm or death. The reports contain categorical data (e.g. age, incident location and severity of harm) and three unstructured free-text fields to encourage reporters to provide a narrative description of the event, perceived causes and potential preventive measures.[26] Incident reports describing severe harm and death outcome are reviewed by healthcare staff and safety experts responsible for the NRLS to identify opportunities for the continuous improvement of care.

Sample selection

The complete data set consisted of 42,729 reports over a period of 8 years (between April 2005 and September 2013) from general practice in England and Wales. We applied the pre-coded NHS categories "Primary care setting" and "Dental surgery" to filter the dataset and obtain a sample of 11,836 records (see Figure 1). From these, we read the narrative descriptions and excluded the reports not related to dentistry. As a result, a revised sample of 4,247 reports was obtained. From this sample, all reports with a "moderate", "severe" and "death" (combined total, n=257) outcome were included. From the remaining "no harm" and "low harm" reports (n=3,990), a random sample of 1,743 reports, weighted by year and the severity of harm, was generated to prioritize more recent (2012-2013) and harmful reports. As a result, a total of 2,000 reports were included for coding. The detailed sampling strategy is shown in Appendix 1.

Methodology

An overview of the methodology is shown in Figure 1. For the first stage, we explored 400 randomly-selected reports and deductively developed initial codes to structure the free-narrative descriptions of the reported incidents. This resulted in three coding frameworks to describe what happened, i.e. type of incident (Appendix 2), perceived reasons the incident occurred, i.e. contributory factors (Appendix 3) and incident outcomes (Appendix 4). These frameworks present a hierarchical arrangement of first- and second-level codes that were continuously refined throughout the study. The codes were constantly compared against categories from other patient safety classification systems. These included the World Health Organization's (WHO) International Classification for Patient Safety,[30] the LINNEAUS Patient Safety Classification for Primary Care,[31] the Primary Care Patient Safety (PISA) Classification System[18] and the results obtained from our previous scoping review.[21] The reports were coded by the first author (EEC). Moreover, a second coder (AS) was trained and provided the same sample of 400 randomly-selected reports and discussed with the main author, the challenges and additional improvements to the coding frameworks. For the second stage, we applied the coding frameworks on our weighted randomized sample of 2,000 reports. Following the method described by Rees et al.,[17] we applied the nine rules of the Recursive Model of Incident

Analysis[32] to structure the coding process (see Appendix 5). Following this approach, we applied between one to four codes in chronological order to describe primary incidents, contributory incidents and contributory factors. The main incident was labelled as a 'primary incident', which was the closest incident to the outcome experienced by the patient. Then, 'contributory incidents' were defined as those incidents preceding the primary incidents. Both primary incidents and contributory incidents were coded in accordance with the incident coding framework (see Appendix 2). A 'contributory factor' was defined as "*a circumstance, action or influence (such as poor rostering or task allocation) which is thought to have played a part in the origin or development of an incident, or to increase the risk of an incident*".[33] Contributory factors were coded in accordance with the contributory factors coding framework (see Appendix 3). Coding of the free-text narrative descriptions allowed the categorization of reports by incident type, potential contributory factors, outcome and severity of harm. This provided the basis for the subsequent data analysis. The severity of harm was assessed using the WHO's International Classification of Patient Safety definitions (see Table 1).[30] To assess the inter-coder reliability, 20% of the reports (n=400) were double coded (EEC and AS). Then, raw agreement and Cohen's K statistics[34] were calculated for the primary incident. A kappa of >0.7 was sought between the two coders. Disagreements in coding were arbitrated by a third person.

Data analysis

For the first stage, during the data coding, the reports were further thematically analyzed and re-read for familiarization. If needed, new codes were created to capture additional semantic (descriptive and in-depth) insights and latent (underlying or inferred) insights present in the narrative descriptions and the circumstances (context) in which the incidents occurred.[35, 36] All codes were grouped into themes and sub-themes to support our understanding of data and the underlying reasons for incidents that might not have been captured by the quantitative data.[35, 36] For the second stage, we undertook an exploratory, descriptive analysis[37] to generate descriptive summaries to identify priority areas based on: (i) the most frequent incidents; and (ii) the most harmful outcomes that resulted in moderate harm, severe harm or death. Following the method used by Rees et al.,[17] we employed pivot tables in Microsoft Excel[38] and cross-tabulated the most frequent incidents per clinical stage with available contributory incidents, contributory factor and their outcomes. We also cross-tabulated the degree of harm against the primary incident types to identify potential relationships in the data. Then, we identified additional patterns in the data by exploring all the frequencies of combinations of incidents and contributory factors (e.g. primary incident + secondary incident + contributory factor).

Ethics

Institutional Review Board approval was obtained from The University of Edinburgh's Centre for Population Health Sciences Research Ethnics Committee.

Results

Of the 2,000 randomized reports, 1,456 were included in the quantitative analysis. Reports were excluded if they did not describe a patient safety incident (n=311), were not related to dentistry (n=125), concerned patient falls (n=31), contained insufficient details (n=23), dentist harmed rather than the patient (n=18), or were about general non-specific complaints (n=6).

Raw agreement (86.5%) and Cohen's kappa (k) statistic for inter-rater coding reliability for primary incidents was high (k=0.860; p<0.01).

Incidents

Table 2 shows a description of the primary incidents we identified. These occurred in the pre-operative (40.3%; n=587), intra-operative (56.1%; n=817) and post-operative (3.6%; n=52) stages of dental care delivery. Main **pre-operative incidents** were delays in treatment (58.6%, n=344), innaccurate information on medical record (10.4%, n=61) and breaches of confidentiality (4.8%, n=28). In the **intra-operative stage,** these included procedural errors (27.8%, n=227), medication-related adverse incidents (161/817; 19.7%) and equipment failure (11.0%, n=90). The more frequent **post-operative incidents** were contraindicated medications prescribed/dispensed (n=15; 28.8%) and errors in the process of delivering a medication (n=12; 23.1%). Regardless of the clinical stage, the main five incident types were *delays in treatment* (23.6%; n=344), *procedural errors (excluding wrong-tooth extraction)* (15.6%; n=227), *medication-related adverse incidents* (11.1%; n=161), *equipment failure* (6.2%; n=90) and *x-ray related errors* (6.0%; n=87).

Contributory incidents and contributory factors

Of the 1,456 primary incidents, 34.8% (n=506) contained data about *contributory incidents*. From these 506, main *contributory incidents* were the dentist´s unavailability (20.2%), equipment failure (14.6%) and mismanagement of appointments (12.6%). Data about *contributory factors* were available in 42.8% (n=623) of the reports. From these 623, main *contributory factors* included distraction (25.5%), insufficient staff members (25.5%) and inadequate skills or knowledge (11.2%). All the possible combinations of primary incidents with contributory incidents and contributory factors organized by clinical stage are available in Appendices 6-8.

In the pre-operative period, frequent *contributory incidents* for **delays in treatment or procedure (n=344)** were the dentist´s unavailability (29.7%, n=102), mismanaging of appointments (16.9%, n=58), and ineffective transportation of patients (7.3%, n=25) (Examples 1 to 3 in Box 1). C*ontributory factors* included insufficient staff members (32.3%, n=111) (Example 4 in Box 1) and lack of equipment maintenance (4.4%, n=15). Secondly, for reports concerning **innaccurate information on records (n=61),** main *contributory incidents* were Information Technology (IT)-related errors (23.0%, n=14) (Example 5 in Box 1). Thirdly, for reports concerning **breaches of confidentiality (n=28),** frequent *contributory incidents* were the inefficient transfer of information between healthcare settings and wrong medical records (7.1%; n=2 each) (Example 6 in Box 1). Main *contributory factors* were failure to adhere to procedures or regulations (50.0%, n=14) (Example 7 in Box 1) and distraction (14.3%, n=4).

In the intra-operative period, c*ontributory incidents* for **procedural errors (n=227)** included equipment failure (9.3%, n=21) (Example 8 in Box 1) and insufficient clinical examination (2.2%, n=5). Main *contributory factors* were distraction (31.3%, n=71) (Example 9 in Box 1), unexpected movement from the patient (10.1%, n=23) (Example 10 in Box 1) and inadequate skills or knowledge (8.8%, n=20). Then, for **medication-related adverse incidents (n=161),** c*ontributory factors* included the patient's previous health-related conditions (13.7%, n=22) (Example 11 in Box 1) and non-compliance from the patient (5.6%, n=9) (Example 12 in Box 1). Lastly, for incidents concerning **equipment failure (n=90),** main *contributory factors* were lack

of equipment maintenance (44.4%, n=40) and poor equipment design (6.7%, n=6) (Example 13 in Box 1). In the post-operative period, *contributory incidents* for **contraindicated medications prescribed/dispensed (n=15)** were insufficient clinical examination (20.0%, n=3) (Example 14 in Box 1). C*ontributory factors* included the patient's previous history on allergies (46.7%, n=7) (Example 15 in Box 1) and staff distraction (20.0%, n=3) (Example 16 in Box 1). **Errors in the process of delivering a medications** (n=10) (Example 17 in Box 1) did not include *contributory incidents or factors.*

Outcomes

Table 3 shows the characterization of incident outcomes. Of the 1,456 incidents, 40.0% (n=583) did not describe an outcome. The more frequent outcomes were *increased documentation/follow-up* (12.4%; n=181), *vasovagal response* (8.2%; n=119), *laceration/bleeding* (6.9%; n=100), *delays in using the dental clinic* (5.8%; n=84), *unnecessary x-ray exposure* (5.1%; n=74) and *repeated procedures/additional treatment* (4.9%; n=72). Cross-tabulations of outcomes (n=1,456) with the degree of harm showed that 97.7% resulted in either no harm or low harm (n=1,379), and only 5.3% were harmful (n= 77). The main harmful ouctomes were unnecessary procedures (44.2%; n=34), anaphylaxis (9.1%; n=7) and vasovagal responses (7.8%; n=6). Cross-tabulations of these harmful outcomes with the primary incidents showed that all harmful reports that resulted in unnecessary procedures (n=34) were due to to *wrong-tooth extractions*. Then, harmful reports involving anaphylaxis (n=7) were mainly due to medication-related adverse incidents (42.9%; n=3) and contraindicated medications prescribed/dispensed (28.6%; n=2). Finally, harmful vasovagal responses (n=6) were mostly due to medication-related adverse incidents (83.3%; n=5).

For the main pre-operative incidents, frequent outcomes for **delays in treatmen**t (n=344) included increased documentation/follow-up (23.3%, n=80) and repeated procedures or additional treatment (5.8%, n=20) (Examples 18 and 19 in Box 1). **Incorrect or unavailable documentation** (n=61) mostly led to increased documentation/follow-up (14.8%, n=9) and delays in using the dental clinic (8.2%, n=5) (Examples 20 and 21 in Box 1). One **breach of confidentiality** resulted in legal implications (3.6%, 1/28;). Secondly, for the main intra-operative incindents, **procedural errors** (n=227) included laceration/bleeding (41.9%, n=95), chemical injuries (9.3%, n=21), repeated procedures/additional treatment (7.5%, n=17) and thermal injuries (6.2%, n=14) (Examples 23 to 26 in Box 1). **Medication-related adverse incidents** (n=161) mostly led to a vasovagal responses (64.0%, n=103) (Examples 27 and 28 in Box 1). **Equipment failure** (n=90) mostly led to delays in using the dental clinic (34.4%, n=31) (Example 29 in Box 1). Finally, for main post-operative incidents, **contraindicated medications prescribed/dispensed** (n=15) led to increased documentation/follow-up and anaphylaxis (20.0%, n=3 each) (Example 30 in Box 1). The majority of the reports concerning errors in the process of delivering a medication did not describe harmful outcomes (75.0%, 9/12).

Discussion

To our knowledge, this is the first mixed-methods study of incident reports from primary care dentistry, identifying the main incident types, their contributory factors and outcomes (clinical and non-clinical). At a conceptual level, our methodological approach aligns with the Swiss Cheese Model of System Accidents proposed by Reason.[39] Moreover, this mixed-methods approach seeks to identify the chronological sequence of events leading up to error by drawing

upon the Recursive Model for Incident Analysis. This approach has been used in general practice[16-18, 40, 41] and has received positive reviews.[42] We drew on a large national database of incidents and achieved very good agreement between two independent coders. Our coding frameworks enabled us to understand the relationships between incident types and contributory factors which highlight opportunities to improve patient safety.

However, we also acknowledge that the reports analyzed likely constitute the tip of the iceberg[43] as these only included events that were actually reported. Although the NRLS has collected over 15 million reports since 2003, less than 1% of these reports originate from primary care.[44] Whilst NHS healthcare professionals might be aware of the NRLS, their fear of punishment from reporting incidents, the time required to report, and the lack of belief that reporting will lead to change are all recognized barriers to reporting.[44] Also, our ability to extract detailed information surrounding context (e.g. demographics and disciplines involved) was limited as the reports were largely unstructured. Renton and Sabbah (2016) also reported this data quality issue.[25] In addition, the free narrative descriptions were often shorthanded and contained abbreviations or other jargon to describe clinical procedures. To bring sense to the data and avoid the risk of confirmation bias,[45] we assigned codes which represented what was explicitly described in the reports; inferences were avoided, in particular when no explicit description was available. Therefore, following the rules from the Recursive Model of Incident Analysis, we coded "primary incidents" as those closest to the outcome. Then, if available, we coded "contributory incidents" as those incidents that preceded the primary incident. We believe this work provides a starting point to systematically characterize future incident reports from primary care dentistry (Appendices 2 to 4).[22, 23, 25, 46-50]

Incidents

In our study, *delays in treatment* were the main pre-operative incidents and remained as the most frequent among all incident types. Although these incidents were not harmful in our study, their presence reveal flaws in the provision of efficient dental care. Nevertheless, delays in treatment can still contribute to diagnostic delays, which can result in the unnecessary clinical deterioration or complication of the patient´s condition or disease.[51] Therefore, we recommend improving administrative processes by understanding the demand for dental care services in the range of care contexts used for delivery. Guidance for the provision of safe, reliable and effective care is available from the Institute for Healthcare Improvement (IHI),[52] including a dentistry-focused IHI Open School course in partnership with the Dental Quality Alliance, established by the American Dental Association.[53]

Our findings also revealed that *procedural errors* were the main intra-operative incidents and the second most frequent among all incident types. Their frequency could be reduced by determining warranted and unwarranted variations in clinical practice. This might be achieved by reviewing compliance with evidence-based or best practice guidelines. However, an emerging threat to patient safety is the increasing complexity of clinical cases and multi-morbidities as the population gets older by living longer.[54] Therefore, as discussed by Hollnagel et al.,[55] clinicians should also have flexibility to adapt their procedures in accordance with the specific needs of the patient being treated. *Equipment failure* was the third most common intra-operative incident and the fourth most frequent among all incident types. This type of incident has been described previously by Perea-Perez et al.,[47] Hiivala et al.[48, 50] and an issue identified from the Food and Drug Administration (FDA) and the Manufacturer and User Facility

Device Experience (MAUDE) database.[56] Based on our findings, we believe equipment-failure incidents can be reduced by having all staff members familiarized with the maintenance processes and assign responsibility to team members to carry out this task on a periodical basis. In identifying patterns of incidents, we also identified *equipment failure* as a "contributory incident" for other "primary incidents" such as *procedural errors* and *errors in obtaining or processing x-rays*. This highlights the interaction of healthcare professionals with sophisticated tools and technologies could increase risk to patient safety,[54] and manufacturers should support practitioners and staff to safely use their equipment.

In our study, *wrong-tooth extractions* were the main source of harmful incidents. Although not frequent (2.7%), these have been studied previously[22, 25] and they meet the criteria of 'never events' due to their severity and degree of preventability.[25, 57] Prevention of these and other incidents can be achieved through the use available procedural checklists[58-61] to reduce reliance on memory and thus, limiting the impact of distraction or inattention in the occurrence of incidents.[62] A recent systematic review on patient safety interventions in dentistry revealed that surgical safety checklists, which covers tooth extractions, demonstrated efficacy to reduce or minimize AEs.[63] We also identified other less frequent intra-operative incidents, which have been also reported in the literature. These include the *inhalation and ingestion of foreign objects,* reported through the review of relatively small samples of adverse event case reports,[49] malpractice cases,[47] and dental patient records.[64] Although not frequent, inhalation of foreign objects alone has recently been proposed as a ´never event´ through international consensus.[65]

Perea-Perez et al.[47] and Hiivala et al.[48, 50] also previously reported similar post-operative incidents. However, incidents related to prescription of medications, or their dispensing, remain largely unreported.[21] Therefore, the evidence base about medication errors in dentistry needs further investigation. Medication errors involving antibiotics for example contribute to antimicrobial resistance worldwide[66] and antimicrobial resistance is an emerging threat to patient safety in the next 30 years.[54] Recently, the World Health Organization (WHO) launched the third Global Patient Safety Challenge to minimize medication related error[67] and dentistry should consider its contribution to this global agenda.

Contributory incidents and contributory factors

The majority of medical errors are due to faulty systems and processes.[8] Reason´s Swiss cheese model of system accidents[39] shows that human errors are often a consequence of latent organizational flaws, such as administrative or management issues. Our findings corroborate this and revealed issues of accessibility to services and mismanagement of appointments, insufficient staff members and lack of equipment maintenance. These issues were mainly related, as a contributory incident or a contributory factor, to patients experiencing delays in receiving treatment, which was the main incident reported to the NRLS. Although these incidents did not lead to harmful outcomes, they reveal the underutilization of primary dental care services. Underutilization of care is a prevalent issue in both high- and low-income economies.[68] Factors contributing to this issue broadly include: a) inaccessible healthcare services to the patient, b) the unavailability of effective services, for instance the result of a lack of resources, c) the clinician's failure to provide effective care, and d) the patients' (inadequate) compliance and adherence to effective healthcare interventions.[68] As the organizational structure of dental care is likely to differ between countries and clinical settings,

we believe quality improvement strategies should be developed and implemented locally. *Distraction* and *unexpected movement from the patient* were the most frequent "contributory factors" for procedural incidents and wrong-tooth extractions. This highlights any unexpected distraction can create conditions for unsafe care. Other reported contributory factors in the literature for wrong-extractions include: i) inadequate checks, ii) incorrect radiographs, and iii) wrong diagnoses have also been reported as causes for wrong-tooth extraction.[25]

Outcomes

Vasovagal responses and lacerations/bleeding were the most commonly described adverse outcomes. However, the majority of outcomes resulted in either no harm or low harm (94.7%; n=1,379) which frequently resulted in increased documentation/follow-up, delays in using the dental clinic, unnecessary x-ray exposure and repeated procedures/additional treatment. The identification of these outcomes showed the presence of flaws in the provision of efficient and effective primary dental care, which in addition to patient safety highlight two further compromised aims of quality improvement, as proposed by the former IOM.[51] Moreover, the over-utilization of healthcare services can: a) contribute to future unnecessary harm; b) result in additional financial demands for the patient; and c) cause waste of resources within the healthcare system.[69]

Our findings have helped to identify priority issues for improvement and are a starting point for setting patient safety research priorities in dentistry.[70] Patient safety in dentistry is still an emerging discipline which needs to be further developed in parallel with the quality of care. Health services researchers designing patient-safety-oriented interventions[51] should consider the more frequent and most harmful incidents reported in this study. Policy makers could take note of these emerging priorities and allocate resources accordingly. We believe this approach will contribute to reduce unintended harm and support appropriate utilization of primary dental care services. Our proposed priority issues can be pursued within research strategies that embrace robust primary research designs and methods with agreed working definitions.[30] Examples of these research designs include mixed methods studies of a mix of complimentary secondary data (e.g. medical records, malpractice cases). In doing so, priority areas and knowledge gaps should be corroborated in local contexts,[71] as well as furthering advances already made for data collection methods and taxonomies for patient safety in dentistry.[72] Natural Language Processing (NLP) could support the pace of progress and in terms of analysing large volumes of data about unsafe dentistry offers a set of informatics tools capable of transforming text into a structured format that can be used for research.[73] For example, data extraction systems based on NLP have been developed in the medical domain.[74] However, this innovation has yet to be explored in dentistry. Incident reporting systems, such as the NRLS in England and Wales, have generated many lessons to improve patient safety. The Council of European Dentists' has already recommended the development of reporting systems in dentistry,[75] and these should now be either developed exclusively for the profession or integrated into existing reporting systems, such as the NRLS, now the Patient Safety Information Management System led by NHS Improvement. Also, any further dentistry-focused initiative needs to be supported by clear regulations and policies that allow private and healthcare-funded dental practices to report incidents, preferably to a single system. Where multiple regulators have complimentary functions in countries, clear processes about incident reporting are needed for the dental profession to follow.[76]

Conclusions

Our study represents an important step forward into the characterization patient safety incidents and their contributory factors in primary care dentistry. Initiatives to improve quality, including patient safety, in dentistry should focus on improving the main sources of unsafe care identified in this work. However, our findings also reveal that over-utilization of dental care services is an issue that can be easily overlooked by researchers, policy makers and members of the dental profession. As more patient safety focused evidence continues to emerge, this needs to be integrated into evidence-based guidelines and compliance with these guidelines needs to be encouraged through fostering a patient safety culture. Patient safety is an emerging field in dentistry that offers a wide spectrum of opportunities for both research and improvement.

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590 # Tables

591 *Table 1. Criteria for describing the severity of harm[30]*

Severity of harm	*Definition*	*Examples in dentistry*
No harm	Patient outcome is not symptomatic, and no treatment is required	Patient's lip got accidentally caught by hand piece bur without any visible injury
Low harm	Patient outcome is symptomatic, symptoms are mild, loss of function or harm is minimal and intermediate but short term, and no or minimal intervention is required	Contact of etching gel to the oral mucosa during procedure
Moderate harm	Patient outcome is symptomatic requiring intervention, an increased length of stay, or causing permanent or long-term harm or loss of function	Fracture of the maxillary or mandible during surgical procedure
Severe harm	Patient outcome is symptomatic, requiring life-saving intervention or major surgical/medical intervention, shortening life expectancy or causing major permanent or long-term harm or loss of function	Non-fatal anaphylactic reaction to local anesthesia that resulted in hospitalization
Death	On the balance of probabilities, death was caused or brought forward in the short term by the incident	Fatal anaphylactic reaction to local anesthesia

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Table 2. Characterization of incidents per degree of harm

Incident types	No harm	Low harm	Moderate harm	Severe	Death	Total	Harmful outcomes (n)	Harmful outcomes (%)
Preoperative stage	**578**	**7**	**1**		**1**	**587**	**2**	0.3
Delays in treatment	343	1				344		0.0
Inaccurate information on medical record	61					61		0.0
Breaches of confidentiality	28					28		0.0
Mismanagement of appointments	19					19		0.0
Ineffective transportation of patients	16					16		0.0
Record not up to date	12	2	1			15	1	6.7
Inefficient transfer of information between settings	15					15		0.0
Referral errors	13	1				14		0.0
Communication errors	14					14		0.0
Insufficient supplies	13					13		0.0
Dentist is not accessible	10					10		0.0
Errors in treatment plan	7	1				8		0.0
Professionalism issue	7					7		0.0
Insufficient clinical examination	6					6		0.0
Wrong medical record	5					5		0.0
Errors in obtaining the informed consent	3	1				4		0.0
Diagnostic errors	2				1	3	1	33.3
Inaccurate laboratory test results	2					2		0.0
Payment issues	2					2		0.0
Failure to follow-up		1				1		0.0
Intraoperative stage	**434**	**311**	**69**	**1**	**2**	**817**	**72**	8.8
Procedural error	78	139	10			227	10	4.4
Medication-related adverse incidents	6	132	21		2	161	23	14.3
Equipment failure	85	5				90		0.0
X-ray related errors	87					87		0.0
Broken instrument	79	4				83		0.0
Ingestion / inhalation of foreign body	36	6				42		0.0
Wrong tooth extracted	2		37			39	37	94.9
Ineffective infection control practices	30					30		0.0
Non-specified procedural complications	6	18	1	1		26	2	7.7
Wrong anatomical side or site treated	6	5				11		0.0
Insufficient supplies	11					11		0.0
Equipment not available	2					2		0.0
Errors in obtaining a biopsy	1	1				2		0.0
Contraindicated dental material used	2					2		0.0
Wrong instrument used	1					1		0.0
Complication as a result of the dental material used		1				1		0.0
Errors in treatment plan	1					1		0.0
Supplies out of date	1					1		0.0
Postoperative	**46**	**3**	**3**			**52**	**3**	5.8
Contraindicated medication prescribed / dispensed	12	1	2			15	2	13.3
Errors in delivering a medication	11		1			12	1	8.3
Prescription errors	10	1				11		0.0
Medication incorrectly stored	5					5		0.0
Unintentional drug overdose (self-administered)	3	1				4		0.0
Medication not available	3					3		0.0
Lost prescription	2					2		0.0
Grand Total	**1058**	**321**	**73**	**1**	**3**	**1456**	**77**	5.3

596 *Table 3. Characterization of outcomes per degree of harm*

Outcome types	Low harm	No harm	Moderate harm	Severe	Death	Total	Harmful outcomes (n)	Harmful outcomes (%)
Incident occurred but no outcome		**582**				**582**		**0.0**
Organizational inconvenience	**14**	**290**	**2**			**306**	2	**0.7**
Increased documentation / follow-up	11	169	1			181	1	0.6
Delays in using the facilities		84				84		0.0
Long wait service		22				22		0.0
Treating patients without sufficient information	2	14				16		0.0
Legal implication	1	1	1			3	1	33.3
Inconvenience to patients (non-clinical)	**15**	**145**	**37**			**197**	37	**18.8**
Unnecessary x-ray exposure		74				74		0.0
Repeated procedures / additional treatment	9	60	3			72	3	4.2
Unnecessary procedures	6	11	34			51	34	66.7
Local outcomes	**144**	**28**	**17**			**189**	17	**9.0**
Laceration/bleeding	89	9	2			100	2	2.0
Chemical injury	14	8				22		0.0
Thermal injury	15		1			16	1	6.3
Localized pain/discomfort	8	6	1			15	1	6.7
Extended paresthesia	6		5			11	5	45.5
Bruises	3	3				6		0.0
Skin tear	4	1				5		0.0
Fracture		1	4			5	4	80.0
Needlestick injuries	3					3		0.0
Necrosis of soft-tissues			2			2	2	100.0
Post treatment infection / abscess			2			2	2	100.0
Affection of the temporomandibular joint	1					1		0.0
Swelling	1					1		0.0
Systemic outcomes	**144**	**12**	**17**	**1**		**174**	18	**10.3**
Vasovagal response	103	10	6			119	6	5.0
Seizure	19	2				21		0.0
Anaphylaxis	11		6	1		18	7	38.9
Difficulty to breathe	7		1			8	1	12.5
Prolonged sleep / unrousable after sedation	3					3		0.0
Cardio-respiratory arrest			2			2	2	100.0
Angina attack			1			1	1	100.0
Methemoglobinemia			1			1	1	100.0
Laryngospasm and bronchospasm	1					1		0.0
Psychological / emotional distress	**4**	**1**				**5**		**0.0**
Death					**3**	**3**	3	**100.0**
Grand Total	**321**	**1058**	**73**	**1**	**3**	**1456**	**77**	**5.3**

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Box 1. Free-text examples of key incidents. *These are extracts from the free-text narrative descriptions of patient safety incidents reported to the National Reporting Learning System. The extracts have been edited by the authors to correct typographical errors and remove indecipherable text.*

Example 1. The dentist rang the clinic, said he was on his way in but had a call to go back home to help with the family (sickness of relative). The dentist said he was sorry for the late call and could we let (person's name) know said he would definitely be in tomorrow.

Example 2. Due to a communication breakdown, the dental nurse and dentist left for an appointment offsite without realizing that the patient, who was due to be seen, had arrived early onsite with her mother and had been overlooked. This meant that the patient was not able to be seen that day.

Example 3. The patient was taken to the wrong clinic by transport and was left with a carer to walk to the actual clinic. The patient was left waiting for 1 hour 50 mins before the transport collected her after 2 phone calls to ask pick up time which was 1120hr - one hour after appointment time. The patient was eventually collected by transport.

Example 4. The dental nurse called in sick. Patients had to be cancelled as an agency nurse was not available. The senior nurse was unable to step in as it was her paperwork day.

Example 5. Patient double booked by dental nurses. The appointment was cancelled at short notice 1 hour prior to scheduled visit. Request to cancel delegated to reception staff. The patient was contacted by consultant and reassurance was given to address this.

Example 6. An email containing identifiable patient information (first name and referral dates) was forwarded to an incorrect staff member due to similar names. The staff member was notified by the sender and deleted the information with immediate action. Provider governance and information governance informed, voice mail left for director of clinical services/line manager. Under pressure from several deadlines and doing more than one task on the PC at once. No surname, address to NHS number were included in this email.

Example 7. During clinical waster audit, 2 black bags opened to look at contents, patients' letter with full details of name, address and all clinical details. Also, patient address labels for another patient. Black waste is destroyed in land fill sites. Breach of confidential information.

Example 8. Stockland Green - whilst patient under sedation undergoing procedure part, the bur detached from hand piece and disappeared suction checked, and mouth checked. Bur not located, procedure stopped, and patient's father was informed.

Example 9. The dentist asked for a saline solution in a syringe to irrigate a socket after extraction. I accidentally gave him sodium hypochlorite in a syringe labelled sodium hypochlorite. I handed the syringe to the dentist which he used to irrigate the socket, then by the smell he realized that it wasn't the saline solution and he informed me. I went and got the saline and put it in a syringe and handed it to the dentist and he used it to irrigate the socket.

Example 10. The floor of the patient's mouth has been cut by a high-speed diamond bur approximately 5mm in length sublingually in LR5 / 6 area. Patient jerked during treatment causing hand piece to slip, thus, causing a wound.

Example 11. The patient attended dental clinic for routine care. Following the administration of local anesthetic, the patient began wheezing. Asthmatic patient.

Example 12. The patient suffered a hypoglycaemic attack at 4:45pm after we had finished dental treatment. The patient had extreme shaking; her speech was extremely slurred. The patient had not eaten since 11:30, the patient felt unwell whilst we were doing dental treatment, but she didn't want to stop us. We observed the patient whilst she recovered and escorted her home. The patient suffered a hypoglycaemic attack and was given to glucose drinks, hypostop and some chocolate.

Box 1. Free-text examples of key incidents. *These are extracts from the free-text narrative descriptions of patient safety incidents reported to the National Reporting Learning System. The extracts have been edited by the authors to correct typographical errors and remove indecipherable text.*

Example 13. A leak from the 3 in 1 equipment. It leaked while a patient was having treatment. The patient was unhappy about getting soaked. I was not noticed sooner that there was a problem with the equipment. The problem with the equipment should have been reported when it was first noticed and not left until a patient made a complaint. Staff meeting held. All staff to report any equipment problems straight away to the practice manager.

Example 14. The patient came to the surgery with pericoronitis on lower right third molar and facial swelling. The patient was given a 1 x 3g amoxicillin sachet, which he took on the spot. We noticed he was allergic to penicillin, he rang his mother, and she informed he once had swelling and rash when he was a child, no incidents since. The patient was informed of this and advised to go to emergencies. The staff rang NHS direct and could not advice on the situation. The patient stayed in the practice for about an hour, and he showed no symptoms of allergy.

Example 15. Patient attended the emergency clinic with a toothache. He was assessed and prescribed amoxicillin. The patient returned the following day as there wasn't any improvement in the pain. The dentist working that session noticed he had been prescribed amoxicillin, but the patient was allergic. The dentist told the patient to stop taking the amoxicillin immediately and prescribed an alternative. The patient was happy with this. He had only taken one of the amoxicillin prescribed.

Example 16. A prescription was made out for Amoxicillin 500mg*21 and Metronidazole 200mg*21. The notes said the patient was allergic penicillin. The patient has a complex medical history. The dentist concentration was on other aspects of the consultation. The dentist realized his prescribing error within a few minutes while writing up patient notes. Staff went out of the building to see if the patient was still nearby. The patient does not have contact telephone numbers. Dentist immediately advised senior colleague and clinical director.

Example 17. The dentist gave a prescription form for a 3g sachet. I dispensed 250mgs capsules. Dentist informed, asked me to contact the patient to return for correct antibiotics.

Example 18. The Senior Dental Officer expected to find the laboratory work for his patient as it was due to be fitted at the next appointment, but it was discovered that it had not been delivered. The Senior Dental Officer telephoned the laboratory, and they informed him that the work in question had gone missing at the lab. The lab suggested that an ex - worker at the premises may have been responsible for the missing work or may have sabotaged the work. The lab apologized, offered to re - start the work and to prioritize the job.

Example 19. I was unable to view a letter regarding a patient on the computer. We tried to read the letter on the computer in the office in (name of clinic) and then on the two computers on the dental reception, but were unable to operate the file, despite clicking on the letter etc. Eventually, a dental nurse was able to access the letter from the clinic. This is unacceptable when trying to view information directly relating to a patient management.

Example 20. Unable to access patient's radiographs from September 09. Attempted at 10:20m, still unavailable 12:25 at the end of appointment. The patient had to be reappointed to complete the treatment plan as a consequence.

Example 21. R4 system is running very slowly and erratically throughout the day. Difficulty in accessing patient records and very difficult writing up notes. Delay in seeing patients and extra work for the clinician. Stressful.

Example 22. Confidentiality breach to GP and family members of HIV status by Dental clinic. Incident being investigated as Serious Incident.

Example 23. Dentist slipped with luxator during dental extraction and cut the lingual artery; the bleeding stopped after 2 sutures.

Example 24. During root canal treatment, a needle containing hypochlorite, came away from the syringe, causing spillage. The patient was wearing rubber dam and safety goggles. However, he felt that some solution

Box 1. Free-text examples of key incidents. *These are extracts from the free-text narrative descriptions of patient safety incidents reported to the National Reporting Learning System. The extracts have been edited by the authors to correct typographical errors and remove indecipherable text.*

had passed into his left eye. Advice was sought from ophthalmology – the eye was washed with running water & saline – the patient is to attend A&E & eye clinic if necessary.

Example 25. The patient stated she had been attending for regular check-ups and declared dentally fit until the single handed general dental practitioner retired. On a recent routine visit to locum dentist, patient told she needs emergency treatment or risks loss of some teeth, crowns poorly fitted and inappropriate anyway, may need dentures, the patient is only in her 40's. Apparent poor performance of previous general dental practitioner.

Example 26. The patient sustained a burn to the lip with heated excavator whilst removing excess of gutta percha. The excavator burnt through the rubber dam but was not noticed as the patient was under local anesthesia. The patient was informed, and Vaseline was applied to the area.

Example 27. The patient was given topical anesthetic followed by infiltration of local anesthetic. After approximately 3-4 minutes, the patient looked unwell, and head started to roll grey and sweaty. No recovery with oxygen and worsened on sitting upright again.

Example 28. I gave a right inferior dental block. A few minutes later, the patient lost consciousness, rolled eyes, went stiff and slumped. The effect lasted less than a minute. The patient was very pale, on regaining consciousness, the patient did not remember. The treatment proceeded uneventfully.

Example 29. I gave the patient local anesthetic, but the portable suction started to fail whilst the nurse was trying to aspirate. Treatment could not be completed in surgery 3. Surgery 1 had a free bay. Therefore, the patient had to be transferred to surgery 1 in order for me to complete treatment. Patient care not affected.

Example 30. Amoxicillin 250mg three times daily was prescribed to the patient for an infected socket after asking whether she was allergic to penicillin. The patient called in approximately half an hour later saying that she has gone red in her face and is itchy on her legs advised to come back immediately. No stridor angioedema or wheezing, itching on her legs. Called GPs downstairs who agreed to see her immediately send patient downstairs with a nurse and she was temporarily registered with the GP practice and was seen by one of the GPs. Called her in the afternoon to see how she was. Patient felt all right. Updated medical history regarding penicillin allergy.

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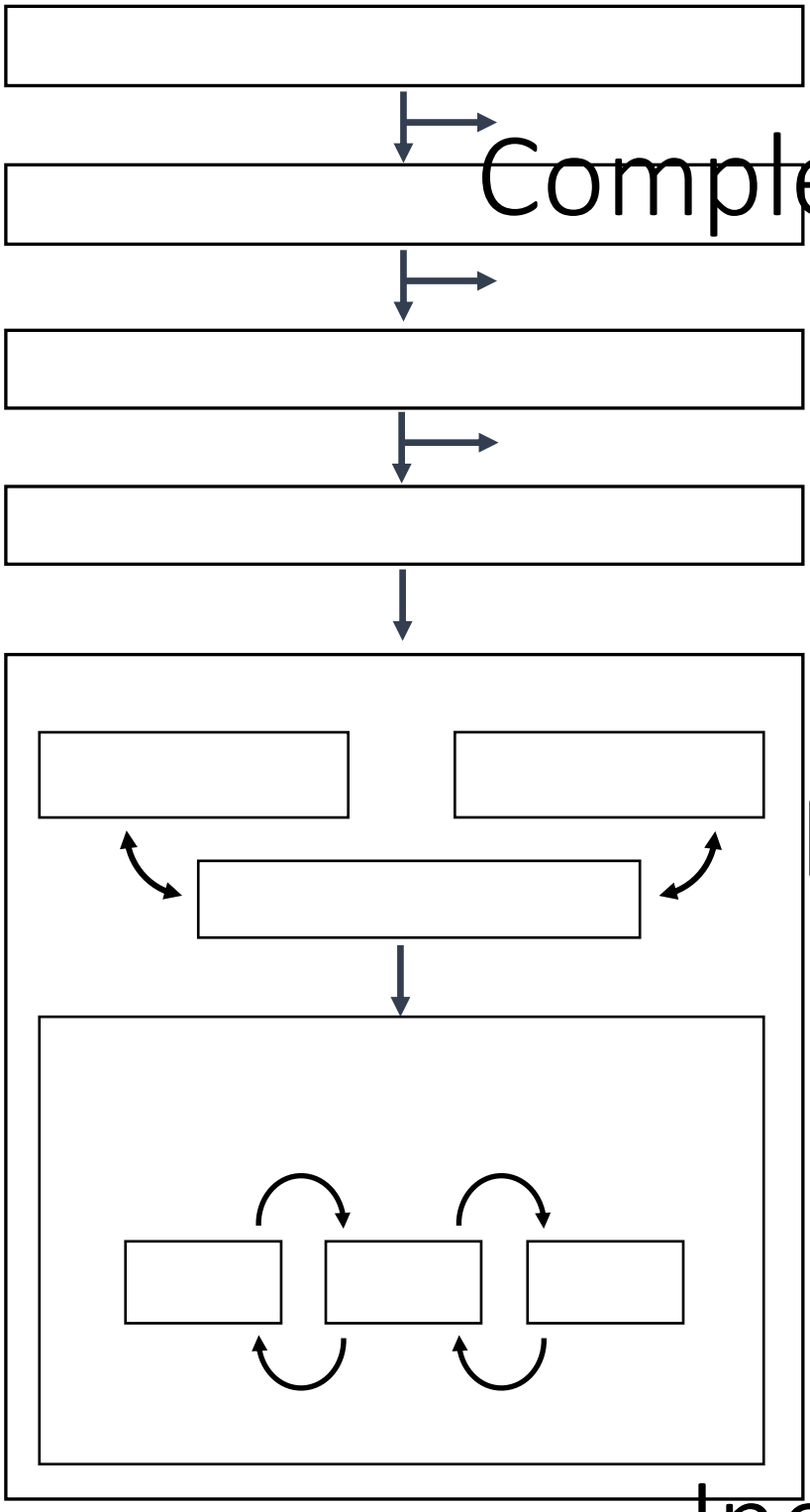
Figure 1. Overview of the methodology



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